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EXAMINER	
KRUER, KEVIN R	

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The time period for reply, if any, is set in the attached communication.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte AJAY K. LUTHRA and SHIVPAL S. SANDHU

Appeal 2009-003329
Application 10/790,338
Technology Center 1700

Decided:[1] July 08, 2009

Before EDWARD C. KIMLIN, BRADLEY R. GARRIS, and ADRIENE LEPIANE HANLON, *Administrative Patent Judges*.

KIMLIN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal from the final rejection of claims 54-104, 151-197, 199-206, and 209-215. We have jurisdiction under 35 U.S.C. § 6(b).

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, begins to run from the Decided Date shown on this page of the decision. The time period does not run from the Mail Date (paper delivery) or Notification Date (electronic delivery).

Claims 54 and 167 are illustrative:

54. A coating for a medical device for delivery of a therapeutic agent, the coating comprising a layer with a thickness between about 0.1 μm and about 1000 μm and having a composition associated with at least a portion of the device, wherein the composition comprises the therapeutic agent associated with copolymer free of covalent crosslinks that has a weight averaged molecular weight of at least about 2500, wherein the copolymer comprises a first monomer unit and a second monomer unit, wherein the second monomer unit has a glass transition temperature that is at least about 30 degrees Centigrade higher than the glass transition temperature of the first monomer unit, with a glass transition temperature of a monomer unit being defined as a glass transition temperature of a homopolymer of that monomer unit.

167. The device of claim 151 wherein the copolymer glass transition temperature is between 26 and 40 degrees Centigrade.

Appellants' claimed invention is directed to a coating for a medical device. The coating comprises a therapeutic agent and a copolymer that is free of covalent crosslinks. The copolymer comprises first and second monomer units wherein the glass transition temperature of the second monomer unit is at least about 30°C higher than the glass transition temperature of the first monomer unit. Also, the glass transition temperature of the copolymer is between 26 and 40°C.

Appealed claims 54-104, 151-197, 199-206, and 209-215 stand rejected under 35 U.S.C. § 112, first paragraph, written description requirement. Claims 54-104, 151-197, 199-206, and 209-215 stand rejected under 35 U.S.C. § 112, second paragraph.

We have thoroughly reviewed the respective positions advanced by Appellants and the Examiner. In so doing, we find that the Examiner's

rejections are not well founded. Accordingly, we will not sustain the Examiner's rejections.

We consider first the rejection under § 112, first paragraph, written description requirement. According to the Examiner, the claim recitation "free of covalent crosslinks" lacks original descriptive support in the Specification, as does the claim recitation defining the glass transition temperature of the copolymer as between 26-40°C.

We agree with Appellants that, although the claim language defining the copolymer as "free of covalent crosslinks" is not explicitly found in Appellants' original Specification, the original Specification reasonably conveys to one of ordinary skill in the art that Appellants had in their possession, at the time of filing the present application, the concept of a coating comprising a copolymer that is free of covalent crosslinks. *In re Edwards*, 568 F.2d 1349, 1351-52 (CCPA 1978). In particular, Appellants' Figures 1A-C illustrate a straight chain copolymer with no crosslinking, and Examples 1-8 of the present Specification describe the preparation of copolymers with mono-unsaturated monomer units that would be expected to produce linear, non-crosslinked copolymers. Since none of the Examples discloses the use of a crosslinking agent in the reaction composition, we concur with Appellants that one of ordinary skill in the art would understand that Appellants had possession of the concept of preparing straight-chained, non-crosslinked copolymers.

The Examiner maintains that the hydroxyl functional methacrylates used in Examples 1-8 of Appellants' Specification "are capable of forming crosslinks with other functional groups in the polymer, with additives such as the therapeutic agent, or with an adjacent layer" (Ans. 6, second para.).

However, the Examiner does not provide any factual support for this assertion, let alone establish that one of ordinary skill in the art would not reasonably expect that the exemplified reactions of Appellants produce a copolymer free of covalent crosslinks. It is of no moment that the exemplified reactions may produce incidental, negligible amounts of crosslinked polymers in addition to straight-chained copolymers that are free of covalent crosslinks. While the Examiner cites U.S. Patent No. 6,530,950 (Alvarado) as evidence that crosslinked polymers are made by reacting monomers consisting of a single double bond (acrylic monomers), the patent to Alvarado depicts non-crosslinked polymers at Figures 1A and 1B, and teaches the use of a crosslinking agent when a crosslinked polymer is produced (*see* col. 8, ll. 4- 23). Again, Appellants' Examples do not include a crosslinking agent.

We are also not persuaded by the Examiner's argument that Appellants' showing of written descriptive support is not commensurate with the claimed invention since the "showing would be to a very narrow class of addition polymers whereas the independent claims are directed to any copolymer (addition polymers or otherwise) meeting the claimed glass transition limitations" (Ans. 7, second para.). The Examiner seems to be confusing claim breadth and the enablement provision of § 112, first paragraph, with the written description requirement. All that is required of Appellants is to demonstrate original descriptive support for subject matter recited in the appealed claims. It is not the function of the claims to exclude inoperable embodiments. *In re Kamal*, 398 F.2d 867, 870 (CCPA 1968).

We also do not subscribe to the Examiner's position that there is no original descriptive support for the lower limit of the claimed range for the

glass transition temperature of the copolymer, namely, 26°C. As acknowledged by the Examiner, Appellants' original disclosure states that the weighted averages for the glass transition temperatures for the copolymers of the present invention are in the range of 0-40°C (*see* Spec. 12, second para.). Furthermore, as pointed out by Appellants, the Specification expressly states that "[p]ersons of ordinary skill in these arts, after reading this disclosure, will appreciate that all ranges and values within these explicitly stated ranges are contemplated" (*id.*). Accordingly, this explicit disclosure in the original Specification, that includes all ranges within the stated range of 0-40°C, reasonably conveys, in our view, that Appellants had in their possession at the time of filing the present application the presently claimed range of 26-40°C.

Regarding the Examiner's § 112, second paragraph rejection, we find no merit in the Examiner's position that "[i]t is unclear how the skilled artisan would go about distinguishing 'covalent crosslinks' from ionic crosslinks since virtually every bond has some ionic and some covalent characteristics" (Ans. 4, third para.). Not only does the Examiner fail to provide factual support for this assertion, but the Examiner has not demonstrated that one of ordinary skill in the art would not reasonably understand the meaning of the claim recitation "covalent crosslinks". As submitted by Appellants "the terms 'ionic' and 'covalent' are commonly used to distinguish different types of bonds" (App. Br. 16, last para.), and therefore, assuming, arguendo, that every bond has some ionic and some covalent characteristics, the Examiner has not established that one of ordinary skill in the art would be unable to distinguish between these types of bonds that are defined in classical chemical textbooks.

In conclusion, based on the foregoing, we are constrained to reverse the Examiner's rejections.

REVERSED

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